



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 10 1986

Re: Buspar
Docket No. 86E-0456

XX/16

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,182,763, filed by Mead Johnson & Company, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Buspar, the human drug product claimed by the patent.

The total length of the review period for Buspar is 5,281 days. Of this time, 3,896 days occurred during the testing phase and 1,385 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: April 16, 1972.

The applicant claims October 22, 1976 as the date that clinical studies on the drug began on. However, FDA records indicate that the notice of claimed investigational exemption (IND) for the drug became effective on April 16, 1972.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: December 15, 1982.

FDA has verified the applicant's claim that a new drug application for the drug (NDA 18-731) was initially submitted on December 15, 1982.

3. The date the application was approved: September 29, 1986.

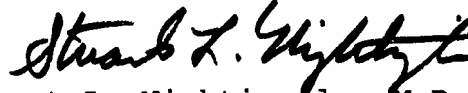
FDA has verified the applicant's claim that NDA 18-731 was approved on September 29, 1986.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent,

nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156 (c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Stuart L. Nightingale". The signature is fluid and cursive, with a prominent "S" and "N".

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Isaac Jarkovsky, Esq.
Assistant General Counsel - Patents
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